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| APPLICATION NO. | FILING DATE | FIRST NAMED INVENTOR | ATTORNEY DOCKET NO. | CONFIRMATION NO. |
|-----------------|-------------|----------------------|---------------------|------------------|
| 10/761,977 | 01/21/2004 | Deen Tulshian | CN0821KD | 4048 |

24265 7590 06/06/2005

SCHERING-PLOUGH CORPORATION
PATENT DEPARTMENT (K-6-1, 1990)
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EXAMINER

RAO, DEEPAK R

| | |
|----------|--------------|
| ART UNIT | PAPER NUMBER |
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1624

DATE MAILED: 06/06/2005

Please find below and/or attached an Office communication concerning this application or proceeding.

| | | | |
|------------------------------|------------------------|---------------------|--|
| Office Action Summary | Application No. | Applicant(s) | |
| | 10/761,977 | TULSHIAN ET AL. | |
| | Examiner | Art Unit | |
| | Deepak Rao | 1624 | |

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 07 March 2005.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 2-12, 19 and 20 ☒ are pending in the application.
- 4a) Of the above claim(s) 5 and 9-12 ☒ are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 2-4, 6-8, 19 and 20 ☒ are rejected.
- 7) ☐ Claim(s) _____ is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 21 January 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
 2. ☐ Certified copies of the priority documents have been received in Application No. _____.
 3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- * See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

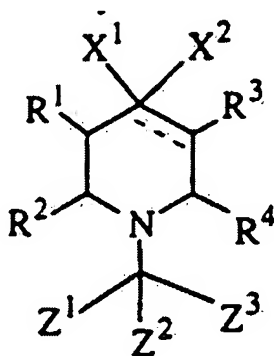
- | | |
|---|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152) |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date <u>01242004</u> . | 6) <input type="checkbox"/> Other: _____ |

DETAILED ACTION

Claims 2-12, 19 and 20 are pending in this application.

Election/Restrictions

Applicant's election without traverse of the species of Table 7, page 53, fifth compound is acknowledged. The species represents a compound of formula as recited in claim 19 (depicted below for convenience) wherein:



R² and R⁴ together form an alkylene bridge and R¹ and R³ are H;

X¹ is phenyl and X² is OH; and

Z¹ and Z² are 2-methylphenyl and Z³ is H.

The elected species reads on claims 19, 20, 2-4 and 6-8.

Applicant is reminded of the election of species guidelines provided in MPEP § 803.02, which are followed for examination. Portion from MPEP is provided here for convenience:

As an example, in the case of an application with a Markush-type claim drawn to the compound C-R, wherein R is a radical selected from the group consisting of A, B, C, D and E, the examiner may require a provisional election of a single species, CA, CB, CC, CD or CE. The Markush-type claim would then be examined fully with respect to the elected species and any species considered to be clearly unpatentable over the elected species. If on examination the elected species is found to be anticipated or rendered obvious by prior art, the Markush-type claim and claims to the elected species shall be rejected, and claims to the non-elected species would be held withdrawn from further consideration. As in the prevailing practice, a second action on the merits on the elected claims would be final.

On the other hand, should no prior art be found that anticipates or renders obvious the elected species, the search of the Markush-type claim will be extended. If prior art is then found that anticipates or renders obvious the Markush-type claim with respect to a nonelected species, the Markush-type claim shall be

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rejected and claims to the nonelected species held withdrawn from further consideration. The prior art search, however, will not be extended unnecessarily to cover all nonelected species. Should applicant, in response to this rejection of the Markush-type claim, overcome the rejection, as by amending the Markush-type claim to exclude the species anticipated or rendered obvious by the prior art, the amended Markush-type claim will be reexamined. The prior art search will be extended to the extent necessary to determine patentability of the Markush-type claim. In the event prior art is found during the reexamination that anticipates or renders obvious the amended Markush-type claim, the claim will be rejected and the action made final. Amendments submitted after the final rejection further restricting the scope of the claim may be denied entry.

The elected species was not found in the prior art search and as per the guidelines above, the examination was expanded to compounds of formula (as shown above) wherein R^2 and R^4 together form an alkylene bridge; R^1 and R^3 are H; X^1 is R^7 -phenyl; X^2 is as defined in the claims; Z^1 is R^5 -alkyl or R^7 -aryl; Z^2 is hydrogen or Z^1 ; and Z^3 is H; and art was found.

Claims 5 and 9-12 are held withdrawn from consideration, pursuant to 37 CFR 1.142(b) as being drawn to non elected invention. All other definitions of the variables R^1 - R^4 , X^1 , X^2 , Z^1 , Z^2 and Z^3 from the generic claims 19, 20, 2-4 and 6-8 are held withdrawn from consideration, pursuant to 37 CFR 1.142(b) as being drawn to non elected subject matter.

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 7-8 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claim 7, in the definition of X^2 , in the term $-NC(O)R^{21}$, the nitrogen has only two attachments to the atom and therefore has an open valency. Further, claim 19 does not have a group consistent with the above term.

Claim Rejections - 35 USC § 103

The following is a quotation of 35 U.S.C. 103(a) which forms the basis for all obviousness rejections set forth in this Office action:

(a) A patent may not be obtained though the invention is not identically disclosed or described as set forth in section 102 of this title, if the differences between the subject matter sought to be patented and the prior art are such that the subject matter as a whole would have been obvious at the time the invention was made to a person having ordinary skill in the art to which said subject matter pertains. Patentability shall not be negated by the manner in which the invention was made.

This application currently names joint inventors. In considering patentability of the claims under 35 U.S.C. 103(a), the examiner presumes that the subject matter of the various claims was commonly owned at the time any inventions covered therein were made absent any evidence to the contrary. Applicant is advised of the obligation under 37 CFR 1.56 to point out the inventor and invention dates of each claim that was not commonly owned at the time a later invention was made in order for the examiner to consider the applicability of 35 U.S.C. 103(c) and potential 35 U.S.C. 102(e), (f) or (g) prior art under 35 U.S.C. 103(a).

Claims 19, 20, 2-4 and 6 are rejected under 35 U.S.C. 103(a) as being unpatentable over Casy et al. (J. Pharm. Pharmacol. 1992) in view of Chang et al., U.S. Patent No. 5,658,908 in combination with Shum et al., U.S. Patent No. 5,495,052.

The primary reference, Casy teaches that 8-azabicyclo[3.2.1]octane compounds have opioid and antinociceptive properties and therefore can be used in pharmaceutical applications, see the reference compounds of formula 10 and pharmacological activity in pages 789-790. The reference does not specifically teach the use of the compounds in treatment of cough.

The secondary reference, Chang et al., in the analogous art teaches compounds having opioid receptor agonist properties, useful in mediating analgesia and also in the treatment of

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various diseases including cough, see col. 1, lines 8-19 and col. 14, lines 45+. Therefore, in view of the teachings of Chang et al., one of ordinary skill in the art at the time of the invention would have been motivated to use the compounds of Ito et al., in a method of treating cough. Such modification would have been obvious because the skilled chemist would have expected the ORL1-receptor agonistic compounds having analgesic activity of Ito et al., to also be useful in the treatment of cough as taught by the Chang reference.

Shum et al., US'052 teaches the use of antitussive guaifenesin in the treatment of cough, see col. 1, lines 14-20. It would have been obvious to one having ordinary skill in the art at the time of the invention to incorporate the teachings of Casy, Chang and Shum and prepare a composition combining the compounds disclosed in Casy with the expectorant, guaifenesin, and use in a method of treatment of cough. One of ordinary skill in the art would have been motivated to combine the teachings of the references because the skilled artisan would have expected the combination to have the same properties and activity taught for the individual compounds as both the compounds are taught to exhibit similar properties. [T]he idea of combining the references flows logically from their having been individually taught in the prior art. *In re Kerkhoven*, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980).

Receipt is acknowledged of the Information Disclosure Statement filed on January 21, 2004 and a copy is enclosed herewith.

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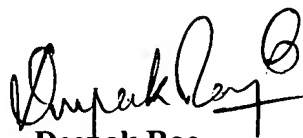
Conclusion

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Deepak Rao whose telephone number is (571) 272-0672. The examiner can normally be reached on Tuesday-Friday from 6:30am to 5:00pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Dr. Mukund Shah, can be reached on (571) 262-0674. If you are unable to reach Dr. Shah within a 24 hour period, please contact James O. Wilson, Acting-SPE of 1624 at (571) 272-0661. The fax phone number for the organization where this application or proceeding is assigned is (571) 273-8300.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is (571) 272-1600.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).


Deepak Rao
Primary Examiner
Art Unit 1624

May 31, 2005